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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,913	09/25/2003	Matthew S. Solar	723.061US1	8466

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EXAMINER

TYSON, MELANIE RUANO

ART UNIT	PAPER NUMBER
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3731

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/671,913

Applicant(s)

SOLAR ET AL.

Examiner

Melanie Tyson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2007.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5, 6, 8-28 and 30-34 is/are pending in the application.
- 4a) Of the above claim(s) 8, 10, 13, 24, 26-28 and 30-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 6, 9, 11, 12, 14-23 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 January 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This action is in response to applicant's amendment received on 05 January 2007. All corrections made are accepted.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 17 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Mowlai-Ashtiani (Patent No. 6,110,182). Mowlai-Ashtiani discloses an alignment device (Figures 1 and 2) comprising a longitudinal guide portion (72) having an opening (where instrument 70 extends), a spherical portion (32), a base unit (80) having a deformable socket (10; via attachment 78; column 3, lines 45-51), an actuating device (52), and a screw retention feature (not labeled; the portion surrounding the two visible screws on base unit 80). The extensions attached to the base unit (80) that extend on both sides of the head of the patient form the "number of standoff features" (right side and left side) since they mount the spherical socket above the work surface to provide access beneath the spherical socket. The portion of the standoff features that holds the large screw (see Figure 1, the screw on the side of the head) comprises the "shelf" portion, since the side portion contains a flat surface in which the head of the screw abuts, or is held.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1-3, 6, 9, 11, 12, 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mocarski (Patent No. 3,073,310) in view of Mowlai-Ashtiani. Mocarski discloses an alignment device (Figures 2, 6, and 8) comprising a longitudinal guide portion (89) having an opening (93; column 4, lines 25-26 and 31-33), a base unit (11) mounted above the skull, and a number of standoff features (13) attached to the base unit (11) located adjacent to a number of securing devices (14; since securing devices 14 are within standoff features 13, they are adjacent, or near the standoff features) and are capable of being placed adjacent to an opening in a skull of a subject along a circle (standoff features are placed around the perimeter of a halo, thus contact the work surface along a circle). The top portion of the standoff features comprises the "shelf"

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portion, since the top portion contains a flat surface in which the head of the screw abuts, or is held. Mocarski does not disclose the base unit (11) has a deformable spherical socket.

Mowlai-Ashtiani discloses an alignment device (Figures 1 and 2). Mowlai-Ashtiani teaches a guide portion (72), a spherical portion (32), a base unit (80) having a deformable socket (10; via attachment 78; column 3, lines 45-51), an actuating device (52), and relief openings (20, 22, and 24). Mowlai-Ashtiani further teaches the device provides symmetric tightening of the spherical socket around the spherical portion (column 2, lines 15-18 and 50-54). It would have been obvious to one of ordinary skill in the art at the time the invention was made to attach the spherical socket device taught by Mowlai-Ashtiani to the base unit of Mocarski in order to provide the user with a greater range of motion, in turn allowing the surgical instrument inserted therein to be accurately aligned with the target within the patient's skull (column 4, lines 48-56).

6. Claims 5 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mocarski in view of Mowlai-Ashtiani as applied to the claims above, and further in view of Hennig (Patent No. 6,328,748 B1). Mocarski in view of Mowlai-Ashtiani discloses an actuating device as described above, but does not disclose the actuating device includes a threaded locking ring. Hennig discloses an alignment device comprising an actuating device (Figure 1; column 6, lines 25-27). Hennig teaches the actuation device includes a threaded locking ring (3) adapted to engage a number of threads (9) coupled to the spherical socket (1; column 5, lines 45-47). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a threaded locking

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ring on the actuating device of Mocarski in view of Mowlai-Ashtiani as taught by Hennig in order to be able to sufficiently hold the spherical portion while providing the best possible range of movement for instruments (column 5, lines 45-50).

7. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mocarski in view Mowlai-Ashtiani as applied to the claims above, and further in view of Ghajar et al. (Patent No. 4,998,938). Mocarski in view Mowlai-Ashtiani discloses the standoff features are truncated (the portion against the skull is parallel to the portion attached to the base), but does not disclose the standoff features are cone shaped. Ghajar et al. teach cone shaped standoff features (wider on top and narrower towards the bottom). It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize cone shaped standoff features in the device of Mocarski in view Mowlai-Ashtiani as taught by Ghajar et al. in order to support the base unit (via the large surface area) and minimize contact with respect to the patient's scalp and cranium (via the smaller surface area) during the procedure, thus reducing the risk of infection to the surrounding tissue (column 2, lines 44-48).

8. Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mowlai-Ashtiani. Mowlai-Ashtiani discloses a screw retention feature (see rejection above), but does not disclose expressly that the screw retention feature includes an elastomer band or a protruding structure located external to and above an opening. At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to utilize an elastomer band or a protruding structure located external to and above an opening. There are numerous retention features well known in the art and

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applicant has not disclosed that an elastomer band or a protruding structure located external to and above an opening provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with the screw retention feature shown in Figure 1 because the function of the feature is to keep the screws from falling out of the base unit and Figure 1 shows the retention features of Mowlai-Ashtiani perform this function. Therefore, it would have been obvious to one of ordinary skill in the art to modify Mowlai-Ashtiani to obtain the invention as specified in claims 18-20.

As requested by the applicant, supplemental references have been provided to show that the screw retention features claimed are well known in the art. For example, Coates et al. (Patent No. 5,423,826) discloses a structure (Figure 6; O-ring 69 formed of biocompatible elastomeric material, thus comprises an "elastomer band"; column 9, lines 39-40) that protrudes into a portion of a screw opening and is strong enough to resist screw pull out (column 9, lines 33-44). Magee et al. (Patent No. 5,957,927) discloses a screw retention feature (retaining element 62, Figure 10; column 5, lines 31-34) that is located external to, and above screw opening (34).

9. Claims 22, 23, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mocarski in view of Mowlai-Ashtiani, and further in view of Hennig. Mocarski discloses an alignment device (Figures 2, 6, and 8) comprising a longitudinal guide portion (89) having an opening (93; column 4, lines 25-26 and 31-33), a base unit (11) mounted above the skull, and a number of standoff features (13) attached to the base unit (11) located adjacent to a number of bone screws (14; since securing devices

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14 are within standoff features 13, they are adjacent, or near the standoff features; see Figure 8) and are capable of being placed adjacent to an opening in a skull of a subject along a circle (standoff features are placed around the perimeter of a halo, thus contact the work surface along a circle). The top portion of the standoff features comprises the "shelf" portion, since the top portion contains a flat surface in which the head of the screw abuts, or is held. Mocarski does not disclose the base unit (11) has a deformable spherical socket.

Mowlai-Ashtiani discloses an alignment device (Figures 1 and 2). Mowlai-Ashtiani teaches a guide portion (72), a spherical portion (32), a base unit (80) having a deformable socket (10; via attachment 78; column 3, lines 45-51), an actuating device (52), and relief openings (20, 22, and 24). Mowlai-Ashtiani further teaches the device provides symmetric tightening of the spherical socket around the spherical portion (column 2, lines 15-18 and 50-54). It would have been obvious to one of ordinary skill in the art at the time the invention was made to attach the spherical socket device taught by Mowlai-Ashtiani to the base unit of Mocarski in order to provide the user with a greater range of motion, in turn allowing the surgical instrument inserted therein to be accurately aligned with the target within the patient's skull (column 4, lines 48-56).

Mocarski in view of Mowlai-Ashtiani does not disclose an insert. Hennig discloses an alignment device (Figure 1). Hennig teaches an insert (Figure 5, element 17) located within a longitudinal opening (10). Figure 1 shows the outer diameter is similar to that of the guide (11), thus fits closely with the opening (10). The inner diameter fits closely with a device to be guided ("specially adapted to" column 6, lines 35-36). It would have

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been obvious to one of ordinary skill in the art at the time the invention was made to utilize an insert in the device of Mocarski in view of Mowlai-Ashtiani as taught by Hennig in order to size the longitudinal opening in the longitudinal guide with the specific equipment that is to be passed there through (column 6, lines 35-36). Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to size the insert to fit closely with a biopsy probe in order to adapt to the probe utilized with the device of Mocarski in view of Mowlai-Ashtiani (column 4, lines 31-34).

Response to Arguments

10. Applicant's arguments with respect to claims 1-3, 5-6, 9, 11-12, 14-16, 17-19, 22-23, and 25 have been considered but are moot in view of the new ground(s) of rejection.

11. Applicant's arguments regarding claims 17, 20, and 21 filed 05 January 2007 have been fully considered but they are not persuasive. Applicant argues primarily that the prior art does not show every element of Applicant's claims. Examiner respectfully disagrees.

Regarding claims 17, 20, and 21, Applicant argues that Mowlai-Ashtiani does not show a screw retention feature of any kind, specifically a screw retention feature to hold a screw in place while also allowing rotation. Figure 1 clearly shows a screw retention feature on the left hand side of the base unit (80), in which two screws lie. Furthermore, the claims do not include the limitation "to hold a screw in place while also allowing rotation" as applicant has argued.

Furthermore, regarding claim 21, Applicant argues that Mowlai-Ashtiani does not show a shelf of any kind. As can be found in the rejection above, the shelf structure has

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been further clarified. To reiterate, the portion of the standoff features that holds the large screw (see Figure 1, the screw on the side of the head) comprises the "shelf" portion, since the side portion contains a flat surface in which the head of the screw abuts, or is held.

12. It is noted that supplemental references (Coates et al. and Magee et al.) have been provided for claims 18-20 just to illustrate that the features claimed are well known in the art (see rejection above).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571) 272-

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9062. The examiner can normally be reached on Monday through Friday 9:00 a.m. - 5:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson 
February 16, 2007


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
